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Research Article

Proposal for Chinese Expert Consensus on Transcutaneous Spinal Cord Stimulation for Painful Diabetic Neuropathy (2024)

Liu Chengjiang[1], Zheng Siyao[1], Liang Yifu[1], Xiang Qiaomin[1, 2], Zhao Wensheng[3], Zhang Aichun[4], Li Yunze[1], Jin Yi[5], Feng Zhiying[1, *]

[1]Department of Painology, The First Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China
[2]Department of Painology, The First Hospital of Ninghai County, Ningbo, China
[3]Department of Painology, Zhejiang Hospital of Integrated Traditional Chinese and Western Medicine, Hangzhou, China
[4]Department of Painology, Sanmen County People's Hospital, Taizhou, China
[5]Department of Painology, Eastern Theater General Hospital, Nanjing, China

Abstract

China has the highest prevalence of diabetes worldwide, leading to substantial healthcare expenditures and a growing burden of diabetes-related complications. Among these, painful diabetic neuropathy (PDN) has become a major public health issue that significantly reduces patients' quality of life. Conventional treatments, such as blood glucose control and pharmacotherapy, provide limited efficacy and benefit only a subset of patients. In recent years, spinal cord stimulation (SCS) has emerged as an effective therapeutic approach for PDN, particularly with the advancement of high-frequency spinal cord stimulation (HF-SCS) technology, which has demonstrated superior clinical outcomes. To address the increasing clinical need for standardized management, the Neuromodulation Professional Committee of the Chinese Medical Doctor Association has developed the *Chinese Expert Consensus on Percutaneous Spinal Cord Stimulation for the Treatment of Painful Diabetic Neuropathy (2024)*. This consensus aims to offer scientific and practical guidance for the clinical application of SCS in PDN. It follows both international and domestic guideline standards and employs the Delphi method and expert panel discussions to formulate evidence-based recommendations. The consensus seeks to optimize treatment strategies, improve patient outcomes, identify existing research gaps, and guide future studies to strengthen the evidence base for standardized PDN diagnosis and management in China.

Keywords

Percutaneous Spinal Cord Stimulation, Painful Diabetic Neuropathy, Guideline, Consensus Document

*Corresponding author: fzy1972@ziu.edu.cn (Feng Zhiying)

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1. Introduction

China has the largest number of diabetes patients in the world and ranks second globally in diabetes-related medical expenditures. The Report on Nutrition and Chronic Diseases of Chinese Residents (2020) indicates a diabetes prevalence of 11.9% in China [1]. The 2021 IDF (International Diabetes Federation) Diabetes Atlas (10th edition) points out that Chinese diabetes patients account for about one-quarter of the global total [2, 3]. Up to 50% of patients develop diabetic neuropathy within several years of diagnosis, and about 30%–50% of these progress to painful diabetic neuropathy (PDN) [4], characterized by stabbing, burning, tearing, electric shock-like pain, and numbness. PDN has a high disability rate, leading to decreased physical function, increased economic burden, and mental health issues such as anxiety, depression, and sleep disturbances, seriously affecting patients' quality of life [5].

In clinical practice, conventional treatment of painful diabetic neuropathy (PDN) primarily focuses on optimizing blood glucose control and administering pharmacotherapy. However, a considerable proportion of patients experience unsatisfactory treatment outcomes or cannot tolerate adverse drug reactions, which severely compromises their quality of life. Spinal cord stimulation (SCS) involves placing stimulation electrodes in the dorsal epidural space of the spinal cord and connecting them to a pulse generator to deliver electrical stimulation to the dorsal column tracts and dorsal horn sensory neurons, thereby achieving therapeutic effects. Neuropathic pain, including PDN, is a principal clinical indication for SCS as approved by both the FDA and CFDA [6]. Although the precise mechanisms underlying the effectiveness of SCS in treating PDN are not yet fully elucidated, its efficacy has been widely demonstrated in clinical practice [7]. In recent years, with the application of novel technologies such as high-frequency spinal cord stimulation (HF-SCS), better treatment outcomes for PDN have been achieved [8]. In 2021, the FDA approved the first 10 kHz high-frequency spinal cord stimulation system (HF-SCS 10 kHz) specifically for the treatment of PDN, making it the first SCS system approved by the FDA with PDN as a distinct indication [9]. Therefore, it is necessary to develop the *Chinese Expert Consensus on Percutaneous Spinal Cord Stimulation for Painful Diabetic Neuropathy (2024)* to address key clinical issues related to patient evaluation, operative techniques, and perioperative management for percutaneous SCS in PDN, clarify the quality of available evidence and recommendation strength, and guide clinical practice.

2. Guideline Development Process and Methods

2.1. Principles

The development of this guideline followed the WHO Handbook for Guideline Development (2014) and the Guidelines for Developing/Revising Clinical Practice Guidelines in China (2022 edition), meeting the AGREE II standards [10]. The protocol and full text will comply with the Reporting Items for Practice Guidelines in Healthcare (RIGHT) checklist [11]. The key steps' technical route is illustrated in Figure 1, and the timeline in Table 1. This guideline was registered on the International Practice Guidelines Registry Platform (http://www.guidelines-registry.cn) with the registration number PREPARE-2024CN773.

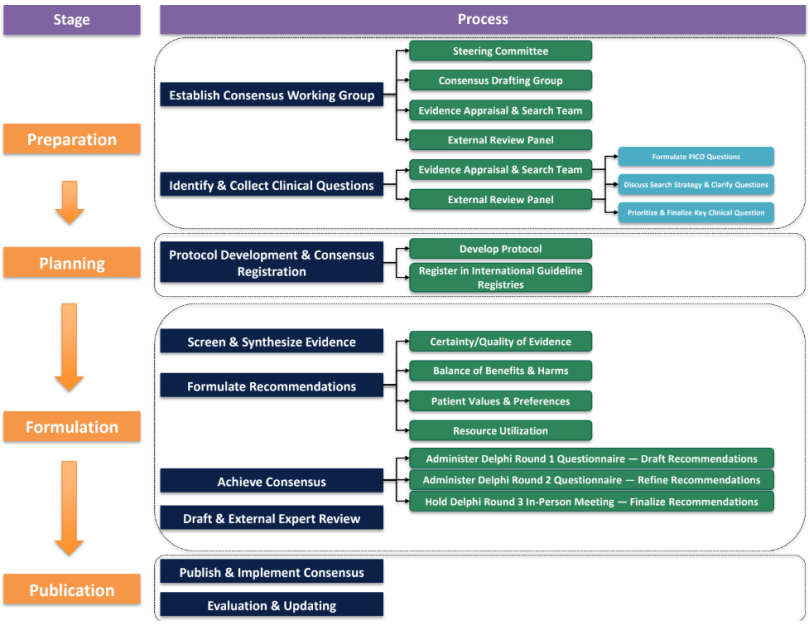

Figure 1. *Consensus Process.*

2.2. Guideline Developing Organization, Target Users, and Applicable Population

To standardize the clinical process and practices of percutaneous SCS for PDN, this guideline was initiated in January 2024 by Prof. Zhiying Feng, Prof. Yi Jin, and Prof. Lingjie Xia, with leadership from the Chinese Medical Doctor Association Neuroregulation Committee. All project members declared conflicts of interest before participating. Intended users include clinicians involved in PDN treatment, such as pain specialists, endocrinologists, neurosurgeons, neurologists, and general practitioners. The target population is PDN patients.

Table 1. *Schedule, Main Leadership Teams, and Work Content for the Formulation of the China Experts' Consensus on Treating Painful Diabetic Neuropathy with Percutaneous Puncture Spinal Cord Electrical Stimulation (2024).*

Stage	Time	Main Leadership Teams	Work Content
Project Initiation and Preparation	January 2024	Secretariat Group	Write the project plan; Register the consensus; Conduct literature review; Conduct small - scale expert interviews. Search, screen, and integrate literature to form the Delphi questionnaire.
	March 2024	Consensus Formulation Group	Hold the kick - off meeting; Discuss issues of the Delphi questionnaire and distribute the 1st round of the Delphi questionnaire. Feed back and summarize experts' opinions to form.
		Guidance Committee	Determine the list of clinical problems.
Formation of the Delphi Questionnaire	April 2024	Guidance Committee	Determine the search strategy, inclusion and exclusion criteria.
		Secretariat Group	Search, screen, and summarize literature.
Delphi Process	June 2024	Consensus Formulation Group, Secretariat Group	Distribute the 2nd round of the Delphi questionnaire. Feed back the 2nd round of the Delphi questionnaire and summarize experts' opinions. Hold a meeting.
Finalization and Release	June - July 2024	Consensus Formulation Group, Secretariat Group; External Expert Review Group of the Secretariat; Guidance Committee	The 3rd round: Determine the consensus recommendation opinions and content through face - to - face discussions. Write the initial draft of the consensus, review, deliberate, and after several rounds of revisions, decide to submit for publication.

2.3. Expert Consensus Working Group

The expert consensus working group consists of four subgroups: the Steering Committee, the Consensus Development Group, the Evidence Evaluation and Secretariat Group, and the External Review Group. The chairs of the Steering Committee are Dr. Xia Lingjie, Dr. Jin Yi, and Dr. Feng Zhiying. The Clinical Chair is the overall leader and primary responsible person for this guideline.

2.3.1. Steering Committee

The Steering Committee is composed of six senior clinical experts and methodological specialists in the field of Percutaneous Spinal Cord Stimulation (SCS) for treating Painful Diabetic Neuropathy (PDN), namely Dr. Feng Zhiying, Dr. Jin Yi, Dr. Xiao Lizu, Dr. Xia Lingjie, Dr. Hu Yongsheng, and Dr. Song Tao. The main responsibilities of the Steering Committee include recruiting experts to form the leadership group for consensus development, administrative support team, and independent evaluation team, assessing and certifying the plan for guideline development, defining the topics and scope for necessary literature research, providing methodological guidance to ensure transparency and quality in the guideline development process, organizing and executing the consensus meeting, reviewing and approving the final guideline text, and resolving any disputes that arise during the guideline development process. The Steering Committee is led by two chairs, responsible for the strategic planning, methodological guidance, team training, and maintaining the overall quality of the guideline, while ensuring that potential conflicts of interest are avoided during the consensus formation process.

2.3.2. Consensus Formulation Group

To ensure the practical guidance of the consensus, and considering the regional differences in medical resources across China, the committee has invited 19 clinical doctors specializing in Percutaneous Spinal Cord Stimulation (SCS) treatment for PDN. These experts include Dr. Jia Yifan, Dr. Fan Yinghui, Dr. Yang Liqiang, Dr. Fan Xiaochong, Dr. Sun Tao, Dr. Chen Fuqiang, Dr. Zhu Qian, Dr. Song Li, Dr. Yang Xiaoqiu, Dr. Lin Fuqing, Dr. Yang Dong, Dr. Feng Zeguo, Dr. Zhao Wensheng, Dr. Ma Ke, Dr. Li Shuiqing, Dr. Zhang Xuexue, Dr. Shen Wen, and Dr. Zheng Yongjun. The main responsibilities of the Consensus Development Group include assessing and defining the scope of the expert consensus, including identifying the scientific basis and necessity for the clinical issues to be included, ensuring broad applicability and effectiveness of the consensus, organizing and executing the Delphi method survey, establishing treatment recommendations through multiple rounds of discussion to form consensus opinions, ensuring the objectivity and comprehensiveness of the treatment recommendations, drafting, reviewing, and revising the consensus guideline text to ensure the scientific accuracy and feasibility of the content, actively promoting the expert consensus through various channels to increase awareness and acceptance, facilitating its clinical application, periodically evaluating and updating the expert consensus to reflect the latest research and clinical practice experience, ensuring the ongoing relevance and effectiveness of the consensus, and organizing and coordinating activities during the consensus development process, ensuring smooth progress while overseeing any potential conflicts of interest to maintain objectivity and fairness. The Consensus Development Group is chaired by Professor Feng Zhiying and Professor Jin Yi, who are responsible for overseeing and driving the development and implementation of the consensus, ensuring high efficiency and quality throughout the process.

2.3.3. Evidence Evaluation and Secretariat

The Evidence Evaluation and Secretariat Group consists of five members, including two clinical professionals, two evidence-based medicine specialists, and one general coordinator. The main responsibilities of the Evidence Evaluation Group include organizing and coordinating the work between various subgroups, including managing online and offline meetings, ensuring effective communication and collaboration during the guideline development process, and accurately documenting meeting content and decisions, overseeing the guideline registration process, including writing detailed guideline plans to ensure transparency and standardization in the guideline development work, conducting research on specific clinical issues, gathering relevant clinical practice and research background information to provide foundational data for evidence evaluation and subsequent recommendation formulation, conducting comprehensive evidence searches, detailed evaluations, and grading, assessing the quality of the collected research evidence based on predefined standards and methods, preparing evidence summary tables, and developing recommendation decision tables to provide scientific support for the final guideline recommendations.

2.3.4. The External Review Group

The External Review Group consists of three clinical pain specialists who were not directly involved in the guideline development. Their main responsibility is to review the formulated recommendations, propose modifications, and provide feedback on the draft guidelines.

2.4. Conflict of Interest and Funding

The working group established a detailed conflict of interest policy, requiring all participants to complete declarations following the WHO conflict of interest disclosure form [12]. Completed declarations will be attached to the guideline or published separately.

2.5. Determination of Clinical Questions and Outcome Indicators

The Evidence Evaluation Group analyzed the latest national and international guidelines and consensus documents related to spinal cord stimulation, combined with recent meta-analyses on SCS for PDN, to create a list of clinical questions [13]. The drafting group reviewed and discussed the questions, scored their importance, and finalized the clinical questions included in the guideline.

2.6. Evidence Retrieval, Evaluation, and Synthesis

A comprehensive search and review were conducted in databases such as PubMed, CNKI, Embase, Cochrane Library, Weipu, and Wanfang, using search terms including "spinal cord stimulation," "spinal cord electrical stimulation," "pinal cord electrical stimulations", "painful diabetic peripheral neuropathy," "diabetic peripheral neuropathy," "diabetic foot," " painful diabetic peripheral neuropathy ", " diabetic peripheral neuropathy ", and " diabetic foot ", with the search period covering from the inception of the databases to January 2024. Researchers from the Secretariat Group conducted a stepwise literature screening based on the title, abstract, and full text in the preliminary search results. They used a pre-designed information extraction form developed by methodology experts to organize and document the number and relevant details of excluded and included studies.

Following the "Oxford Centre for Evidence-Based Medicine 2011 Evidence Quality Table" [14], studies were selected based on their evidence quality, ranked from high to low. Narrative reviews, case series, case reports, conference

abstracts, and registered but incomplete studies were excluded. The GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach was used to rate the supporting evidence for the recommendations. According to the GRADE method, the evidence quality was categorized into four levels: high, moderate, low, and very low. Randomized controlled trials (RCTs) were considered high-quality evidence, while observational studies were regarded as low-quality evidence. After the evidence grading was completed, the evidence was presented in a summary table. The final guideline included 66 RCT articles, with the remaining evidence drawn from expert consensus, guidelines, or reviews.

2.7. Clinical Questions and Recommendations

The methodology of this consensus primarily includes literature review, clinical question formulation, modified Delphi method, expert panel discussions, and consensus revisions. Based on the results of the literature search and the PICO principle, the working group constructed clinical questions covering six areas of interest, encompassing a total of 11 aspects, as follows: (1) the definition, epidemiology, clinical presentation, and key diagnostic points of PDN; (2) the efficacy and mechanisms of SCS in treating PDN; (3) the cost-effectiveness and economic considerations of SCS in treating PDN; (4) indications and contraindications for SCS treatment of PDN. After discussions with experts Song Tao, Hu Yongsheng, Xiao Lizu, and Xia Lingjie, the authors, Feng Zhiying and Jin Yi, designed the questionnaire.

After completing the evidence summary table, the guideline development group formed preliminary recommendations based on evidence quality, patient preferences and values, health economics analysis, and benefit-risk balance, and determined the strength of the recommendations. Consensus on the recommendations and their strength was reached through two rounds of the Delphi method and three rounds of online or offline discussions. The rules for reaching consensus were as follows: if more than 75% of the participating experts agreed on a recommendation, consensus was reached [15]; for recommendations not reaching consensus, revisions were made based on expert opinions, followed by a second round of Delphi consensus or discussion until consensus was achieved or the recommendation was removed from the guideline. Once consensus on a recommendation was reached, it was submitted for approval by the Steering Committee. With approval from 75% of the guideline development group members, the Steering Committee could revise and refine significant issues in the recommendation, and the evidence evaluation group would accurately record the entire revision process. The strength of the expert consensus recommendations was classified based on the percentage of expert agreement: 80%-100% as a strong recommendation, 60%-80% as a moderate recommendation, and <60% as a weak recommendation, as shown in Table 2.

Based on the results of expert panel discussions, the consensus draft was further revised to ensure its scientific accuracy, rationality, and feasibility. Through soliciting opinions, incorporating feedback, and revising drafts, the accuracy of the consensus content was ensured, and the final revised consensus was designed to provide strong practical guidance. The methodology of this consensus aims to provide scientific, reasonable, and practical guidelines for researchers, clinicians, and patients in the relevant fields. Through the implementation of this process, it ensures that the expert consensus has high internal quality and external value. This consensus underwent three rounds of meetings to form the initial draft, followed by three rounds of revisions, and was ultimately reviewed and discussed by the editorial board before the final version was completed.

2.8. External Review and Approval

Consensus recommendations were reviewed by the external expert group. Feedback was discussed by the drafting group and incorporated as appropriate. The final recommendations were approved by the Steering Committee.

2.9. Guideline Publication and Updates

After the recommendation was approved, the guideline draft was strictly written according to the international health practice guideline reporting standards (Reporting Items for Practice Guidelines in Healthcare, RIGHT) and resubmitted for approval by the Steering Committee. The full guideline is expected to be published in relevant journals between 2024 and 2025. An update to the guideline is planned for 3–5 years later. The primary considerations for updating the guideline will include whether new evidence from evidence-based medicine has emerged, whether new clinical questions need to be added, and whether significant changes in factors affecting the recommendations have occurred.

2.10. Dissemination, Implementation, and Evaluation

After the guideline is published, it will be primarily disseminated and promoted through the following methods: (1) introduction in professional journals, websites, and academic conferences; (2) planned promotional activities in certain provinces, aimed at ensuring that clinicians, pharmacists, and nurses fully understand and accurately implement the guideline recommendations. Additionally, an evaluation will be conducted 1 to 2 years after the guideline's release to assess its impact on the current state of diabetic neuropathy diagnosis and treatment in China, explore the effectiveness of its dissemination, and examine its role in clinical decision-making.

Table 2. Evidence Levels and Recommendation Grades of the Recommendation Opinions.

Level	Description
High (A)	Further research is unlikely to change the credibility of the efficacy evaluation result
Moderate (B)	Further research is very likely to affect the credibility of the efficacy evaluation result and may change the evaluation result
Low (C)	Further research is extremely likely to affect the credibility of the efficacy evaluation result, and the evaluation result is very likely to change
Very Low (D)	Any efficacy evaluation result is very uncertain
Strong Recommendation (1)	Consensus with unanimous agreement (supporting opinions ≥ 80%)
Weak Recommendation (2)	Basic consensus with minor disputes (supporting opinions 60% - 80%)
No Consensus (3)	No consensus with major disputes (supporting opinions < 60%)

3. Discussion

Diabetic neuropathy is the most common chronic complication of diabetes and one of the major risk factors for diabetic foot. Early prevention and treatment of diabetic neuropathy are crucial for improving patients' quality of life and reducing disability rates. For painful diabetic neuropathy (PDN) with poor drug efficacy, percutaneous spinal cord stimulation (SCS) has become an important treatment option. However, there are still many controversies regarding its use, such as when to initiate SCS implantation [16], perioperative evaluations—especially blood glucose and anticoagulant management [17, 18]—and how to assess the effectiveness of SCS treatment [16]. Furthermore, there are questions about how to manage SCS treatment more effectively and long-term [7, 16]. Therefore, the Neuromodulation Committee of the Chinese Medical Association, in collaboration with domestic and international experts, initiated the development of the "Chinese Expert Consensus on Percutaneous Spinal Cord Stimulation for Painful Diabetic Neuropathy" to re-evaluate and make recommendations on these controversial clinical issues.

This consensus was developed based on clinical needs and issues, incorporating the latest evidence from evidence-based medicine along with the practical situation in China to create a PDN treatment plan with Chinese characteristics. During the development process, we also found that a small number of clinical issues lacked sufficient evidence, making it difficult to provide clear recommendations. Therefore, while this consensus offers feasible treatment recommendations, it also highlights research gaps in these areas and identifies future research directions. It encourages the academic community and clinicians to conduct more research on these critical issues so that more accurate and comprehensive treatment guidelines can be provided in the future.

Through the publication and implementation of this consensus, we hope to further standardize clinical practice in percutaneous spinal cord stimulation for PDN, optimize treatment outcomes, alleviate patient suffering, and improve quality of life. At the same time, we look forward to future research continually enriching and improving this consensus, enabling it to better serve clinical practice and patient health.

Abbreviations

PDN	Painful Diabetic Neuropathy
SCS	Spinal Cord Stimulation
FDA	U.S. Food and Drug Administration
NMPA	National Medical Products Administration (China)
CFDA	China Food and Drug Administration
HF-SCS	High-Frequency Spinal Cord Stimulation
AGREE II	Appraisal of Guidelines for Research & Evaluation II
RIGHT	Reporting Items for Practice Guidelines in Healthcare
EBM	Evidence-Based Medicine
PICO	Patient/Problem, Intervention, Comparison, Outcome
GRADE	Grading of Recommendations Assessment, Development and Evaluationg

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Conflicts of Interest

The authors declare no conflicts of interest.

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